

The Plastics Industry Trade Association

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September 30, 2002

Christine Todd Whitman, Administrator U. S. Environmental Protection Agency P.O. Box 1473 Merrifield, VA 22116

Attention: Chemical Right-to-Know

RE: Test Plans and Robust Summaries for Alkyl (C₁₂-C₁₄) Glycidyl Ether (CAS No. 68609-97-2) and n-Butyl Glycidyl Ether (CAS No. 2426-08-6)

Dear Ms. Whitman:

On July 29, 2002, the Society of the Plastics Industry, Inc. (SPI), on behalf of its Epoxy Resin Systems Task Group (ERSTG), received comments on the test plans and robust summaries for alkyl (C₁₂-C₁₄) glycidyl ether and n-butyl glycidyl ether that were submitted to EPA under the U.S. EPA High Production Volume (HPV) Challenge Program.

Attached are revised test plans and robust summaries that address comments received on these documents. In summary:

Alkyl (C₁₂-C₁₄) glycidyl ether

- Robust summaries are provided for the physicochemical endpoints
- A water solubility study is added to the test plan
- The fugacity robust summary is revised to reflect user-entered data for the vapor pressure that is consistent with the vapor pressure robust summary; there is no resulting change on the output
- The repeated-dose and developmental toxicity robust summaries are revised to include quantitative data. Additionally, neither the 2-week nor the 13-week repeated-dose toxicity test reports included a protocol or state whether collars (e.g. Elizabethan) were attached to the animals; it is only stated that test sites were non-occluded. However, the reports state that the animals were housed one per cage (i.e. individually) throughout the duration of the test.

N-butyl glycidyl ether

- Robust summaries are provided for the physicochemical endpoints
- The fugacity robust summary is revised to reflect user-entered data for the water solubility and vapor pressure that are consistent with the water solubility and vapor pressure robust summaries.
- The ecotoxicity robust summaries are revised to include additional information requested regarding analytical measurements and test concentrations; test substance purity is not provided in the reports.

- Health effects acute toxicity:
 - A total of three acute oral studies/data were reviewed, only one of which is determined to contain sufficient information to be graded at least a Klimisch 2. The other two studies were reviewed; robust summaries were written and have been provided. They validate the results of the submitted study, namely, that the acute oral LD50 in rats is >2 grams/kg. The totality of the information on acute oral toxicity in rats is consistent; all of these data demonstrate that n-butyl and t-butyl glycidyl ether produce mortality at 2 g/kg, with LD50s of 2.05 (1.56-2.69), 2.26, and 2 g/kg. We do not believe that additional testing is warranted since such testing would only serve to validate information that has already been determined.
- An in vitro chromosomal aberration study was added to the test plan
- The repeated-dose toxicity robust summary is revised to include quantitative data for both the 28-day and 90-day studies; the NOAELS for all three species in the 90-day study are reassessed and 25 ppm is been recommended as a LOAEL for mice and rabbits
- The ERSTG notes EPA's agreement that a reproductive/developmental toxicity study is needed, but would prefer to retain the original recommendation of OECD Test Guideline 414 instead of the screening test (OECD Test Guideline 421).

Please contact me at 202-974-5217 or e-mail me at lharris@socplas.org to forward comments, if you have further questions or require additional information.

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Lyane R. Harris Executive Director Epoxy Resin Systems Task Group

cc w/o attachments: C. Auer, EPA

R. Hefter, EPA

O. Hernandez, EPA B. Leczynski, EPA

R. Northrop, EPA

F. McEldowney, American Chemistry Council

Attachments